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Philogen
innovating targeting

Philogen Announces Clinical Trial Collaboration with MSD

The Phase II clinical trial investigates Philogen's immunocytokines (i) L19IL2 (ii) L19TNF, and (iii) Nidlegy™ in combination with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in stage III and IV unresectable melanoma patients who previously failed treatment with checkpoint inhibitors

Siena, Italy, June 1st, 2023 - Philogen S.p.A., a clinical-stage biotechnology company focused on the development of innovative medicines based on tumor-targeting antibodies and small molecule ligands, announces that it has entered into a Clinical Trial Collaboration and Supply Agreement with MSD (Merck & Co., Inc., Rahway, NJ, USA). Under the terms of the supply agreement, MSD provides their anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), to be evaluated in combination with Philogen's immunocytokines L19IL2, L19TNF, and Nidlegy™ in a randomized Phase II clinical trial. The study provides an opportunity to explore the combination of immunocytokines and PD-1 blockade in stage III and IV unresectable melanoma patients who failed prior checkpoint inhibitor therapies.

Nidlegy™ is also investigated in two Phase III randomized clinical trials for the treatment of stage III B/C melanoma in Europe and in the United States, as well as in two Phase II clinical trials in High-Risk Basal Cell Carcinoma and other non-melanoma skin cancers.

Dario Neri, CEO and CSO of Philogen, commented: "KEYTRUDA® has shown impressive response rates and long-term benefits for a substantial number of patients with advanced melanoma. However, only a minor proportion of patients who fail checkpoint inhibitors typically benefit from a subsequent re-challenge with single-agent PD-1 blockade. Clinical experience with intralesional recombinant IL2 has shown encouraging response rates when combined with systemic anti-PD-1 antibodies in advanced melanoma patients who progressed on or are resistant to checkpoint inhibitors. This provides a strong rationale to combine Nidlegy™ (L19IL2 + L19TNF) with KEYTRUDA® in this setting, and we are pleased to partner with MSD, a global leader in immuno-oncology, to explore this opportunity."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.
Nidlegy™ is a registered trademark of Philogen S.p.A. of La Lizza 7, 53100 Siena, ITALY.

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Philogen Group Description

Philogen is an Italian-Swiss company active in the biotechnology sector, specialized in the research and development of pharmaceutical products for the treatment of highly lethal diseases. The Group mainly discovers and develops targeted anticancer drugs, exploiting high-affinity ligands for tumor markers (also called tumor antigens). These ligands - human monoclonal antibodies or small organic molecules - are identified using *Antibody Phage Display Libraries* and *DNA-Encoded Chemical Library* technologies.

The Group's main therapeutic strategy for the treatment of these diseases is represented by the so-called *tumor targeting*. This approach is based on the use of ligands capable of selectively delivering very potent therapeutic active ingredients (such as pro-inflammatory cytokines) to the tumor mass, sparing healthy tissues. Over the years, Philogen has mainly developed monoclonal antibody-based ligands that are specific for antigens expressed in

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tumor-associated blood vessels, but not expressed in blood vessels associated with healthy tissues. These antigens are usually more abundant and more stable than those expressed directly on the surface of tumor cells. This approach, so called *vascular targeting*, is used for most of the projects pursued by the Group.

The Group's objective is to generate, develop and market innovative products for the treatment of diseases for which medical science has not yet identified satisfactory therapies. This is achieved by exploiting (i) proprietary technologies for the isolation of ligands that react with antigens present in certain diseases, (ii) experience in the development of products targeted at the tissues affected by the disease, (iii) experience in drug manufacturing and development, and (iv) an extensive portfolio of patents and intellectual property rights.

Although the Group's drugs are primarily oncology applications, the *targeting* approach is also potentially applicable to other diseases, such as certain chronic inflammatory diseases.

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